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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,446	10/03/2001	Franck J. Barrat	DX01177	9613

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EXAMINER

BELYAVSKIY, MICHAIL A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 11/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

RR, response due
12-18-02

RECEIVED

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Patent Department

Office Action Summary

Application No.

09/970,446

Applicant(s)

BARRAT ET AL.

Examiner

Michail A Belyavskyi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending.

Restriction Requirement

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 -14, drawn to a method comprising contacting naive T cells with stimulatory signal and an appropriate amount of a combination of vitamin D3 and dexamethasone, wherein stimulatory signal is activation with antigen and antigen presenting cells and wherein said regulatory cell suppresses response to a defined antigen and a population of said cells, classified in Class 435, subclasses 41 and 325.

II. Claims 1 -14, drawn to a method comprising contacting naive T cells with stimulatory signal and an appropriate amount of a combination of vitamin D3 and dexamethasone, wherein stimulatory signal is activation with antigen and antigen presenting cells and wherein said contacting occurs in the presence of an antagonist of IL-4, of IFN-gamma, and/or IL-12 and a population of said cells, classified in Class 435, subclasses 41 and 325.

III. Claims 1-3 and 5-14, drawn to a method comprising contacting naive T cells with stimulatory signal and an appropriate amount of a combination of vitamin D3 and dexamethasone, wherein stimulatory signal is anti-CD3 and anti-CD28 and wherein said regulatory cell suppresses response to a defined antigen and a population of said cells, classified Class 435, subclasses 41 and 325.

IV. Claims 1-3 and 5-14 drawn to a method comprising contacting naive T cells with stimulatory signal and an appropriate amount of a combination of vitamin D3 and dexamethasone, wherein stimulatory signal is anti-CD3 and anti-CD28 and wherein said contacting occurs in the presence of an antagonist of IL-4, of IFN-gamma, and/or IL-12 and a population of said cells, classified in Class 435, subclasses 41 and 325.

V. Claims 1, 15-16 , drawn to a method comprising contacting naive T cells with stimulatory signal and an appropriate amount of a combination of vitamin D3 and dexamethasone and administering said cells to an animal, classified in Class 424, subclass 93.1.

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VI. Claims 17-19 drawn to method comprising administering regulatory T cells specific for an exogenous antigen to an animal, classified in Class 424, subclass 93.7.

2. Groups I- VI are different methods. These inventions are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

3. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

4. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

5. If Groups II or IV are elected, applicant is required to elect a specific method comprising contacting naive T cells with stimulatory signal, wherein contacting occurs in the presence of a specific antagonist recited in claim 10 (b).

These species are distinct because a specific method comprising contacting naive T cells with stimulatory signal and an appropriate amount of a combination of vitamin D3 and dexamethasone, wherein contacting occurs in the presence of a specific antagonist, recited in claim 10 (b) differ with respect to the specific antagonist and the endpoint of the method; thus each specific method employing a specific antagonist represents patentably distinct subject matter. Furthermore, the examination of specific antagonist recited in the claim 10(b) would require different searches in the scientific literature.

6. If Groups V or VI are elected, applicant is required to elect a specific method comprising administering regulatory T cells to an animal, wherein said animal undergoing an:

- A) inflammatory pathology, or
- B) autoimmune pathology.

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These species are distinct because a specific method comprising administering regulatory T cells to an animal, wherein said animal undergoing a specific pathology differ in etiologies and therapeutic endpoints of pathological conditions; thus each condition represents patentably distinct subject matter.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
November 18, 2002


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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